

## REMARKS

### *Status of the Claims*

Claims 17, 21-24, 26, 28, 29, 31, 33, 38, and 42 are in the application.

Claims 17, 21-24, 26, 28, 29, 31, 33, 38, and 42 have been rejected.

Claims 17 is hereby amended to better define the invention. No new matter has been added.

Upon entry of this amendment, claims 17, 21-24, 26, 28, 29, 31, 33, 38, and 42 will be pending.

### *Arguments*

#### *Rejection under 35 USC §103*

Claims 17, 21, 24, 26, 28, 29, 31, 33, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alila et al. in view of Draghia-Akli, Fewell et al, Goncalves (Cardiovascular Res., 45: 294-302, 2000), Nicosia et al. (American J. of Pathology, 145(5): 1023-1029, 1994) and Isner.

MPEP § 2143 provides that obviousness requires some suggestion or motivation in the reference themselves, or in the general knowledge of a skilled artisan, to modify the reference or to combine reference teachings to yield a reasonable expectation of success. It is respectfully submitted that the cited references, either alone or in combination, fail to render the claimed invention obvious.

The claimed invention as amended relates to a promoter having sequence of SEQ ID NO:3. Neither Alila, Draghia-Akli, nor any of the other cited references, alone or in combination, teach the claimed invention. Specifically, SEQ ID NO:3 is comprised of a 323 bp sequence that can be found in the Specification and Sequence Listing, as filed. Draghia-Akli does not teach SEQ ID NO:3, but rather discloses only a sequence identified and described as a

360 bp SacI/BamHI fragment of a SPc5-12 synthetic promoter. As admitted on Page 4 of the outstanding Office Action, Alilia et al fails to teach a synthetic myogenic promoter that comprises SEQ ID NO:3, and Draghia-Akli, while teaching a 360bp promoter, fails to teach the exact promoter of 323 bp that is SEQ ID NO:3. One of ordinary skill in the art would have to practice undue experimentation to practice the claimed invention, even with Draghia-Akli available to him/her. There are no teachings in the art that would suggest what fragment or variant of the 360bp promoter taught in Draghia-Akli would function as a promoter and with the beneficial properties of the promoter SEQ ID NO:3. Furthermore, none of Fewell, Goncalves, Nicosia, nor Isner are cited for any teaching related to muscle-specific promoters and do not appear to disclose SEQ ID NO:3.

Accordingly, the claimed invention is neither taught nor suggested by the cited references in combination, and a prima facie case of obviousness has not been made. Reconsideration and withdrawal of the rejection under 35 U.S.C. 103(a) are respectfully requested.

Claims 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alila et al. (cited above) in view of Draghia-Akli (cited previously), Fewell et al (cited previously), Goncalves (Cardiovascular Res., 45: 294-302, 2000, Nicosia et al. (American J. of Pathology, 145(5): 1023-1029, 1994) and Isner (cited previously) as applied to claims 17, 21, 24, 26, 28, 29, 31, 33, 38, 41, 42 above, and further in view of van Deutekom et al. (Mol. Med. Today, 214-220, May 1998).

Based on the argument provided, above, and considering that van Deutekom is not cited for and fails to disclose anything related to SEQ ID NO:3, Applicants submit that the cited references, alone or in combination, fail to render the claimed invention obvious.

Accordingly, claims 22 and 23 are not obvious over the cited art, and thus Applicants respectfully request the rejection be withdrawn.

In conclusion, the Applicants submit that all pending claims are in condition for allowance and request an early indication of the same. Should the Examiner have any questions that may be addressed through a teleconference, the Examiner is invited to contact the undersigned attorney.

The Commissioner is hereby authorized to charge any additional fees which may be required by this paper, or credit any overpayment to Account No. 50-4992.

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